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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,861	03/05/2001	James R. Broach	CPI-012C8US	4402
959	7590	07/21/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			CELSA, BENNETT M	
			ART UNIT	PAPER NUMBER
			1639	
DATE MAILED: 07/21/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/581,861	<b>Applicant(s)</b> BROACH ET AL.	
	<b>Examiner</b> Bennett Celsa	<b>Art Unit</b> 1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-61 and 109-119 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-61 and 109-119 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 1-61 and 109-119 are presently pending.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1(in part), 4, 6-8 and 26, drawn to recombinant yeast comprising a heterologous G protein coupled receptor (GPCR) and substituted heterologous G protein subunit.

Group 2, claim(s) 1(in part), 5, 9-25, drawn to recombinant yeast comprising heterologous GPCR and chimera of STE18 and heterologous G (gamma) subunit.

Group 3, claim(s) 1(in part), 2 (in part), 3, 44-61, drawn to recombinant yeast comprising heterologous GPCR and chimera of GPA1 ( $\leq 4$  c-terminal substituted with heterologous G protein subunit amino acids) and optionally linked to at least the 1<sup>st</sup> five amino acids of a 2<sup>nd</sup> heterologous G protein subunit.

Group 4, claim(s) 27 and 28, drawn to an assay for identifying modulators of G (alpha) and G (beta-gamma) dissociation.

Group 5, claim(s) 29-43, drawn to an assay for identifying modulators of heterologous GPCR.

Groups 6-16, claim(s) 109-119, drawn to peptides comprising sequences 107-115, 118 and 123, respectively.

The inventions listed as Groups 1-15 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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Groups 1-3 do not share a common special technical feature since recombinant yeast cells comprising fusions between heterologous G-Protein coupled receptors (GPCR) and chimeric G protein subunits (e.g. yeast/mammals) are known in the art. See e.g. King et al. US Pat. No. 5,482,835 and Kang (1990 Mol. Cell. Biol. 10:2582-2590) cited in the specification. Additionally the Markush of "chimeric G-subunits" present in claim 1 and found in Groups 1-3 lack a common (e.g. core) structure present as to constitute a "significant structural element shared by all of the alternatives needed to elicit a common property of activity". See e.g. MPEP Annex B: Unity of Invention Part 1 "Instructions Concerning Unity of Invention.". Similarly, the peptides of Groups 6-15 lack the same or corresponding special technical features since the individual peptide sequences lack common (e.g. core) structure present as to constitute a "significant structural element shared by all of the alternatives needed to elicit a common property of activity". The methods of Groups 4 and 5 lack the same or corresponding special technical features since the methods are drawn to different method objectives, utilize diverse reagents and reaction conditions.

***Election of Species (For Groups 1-5 ONLY)***

1. This application contains claims drawn to the following patentably distinct species of the claimed invention:

Yeast fusion constructs comprising:

- a. a heterologous G protein-coupled receptor;
- b. "chimeric G protein-coupled receptor"

Individual fusion proteins comprising the above fusion constructs are structurally different; have different physicochemical properties; are capable of separate manufacture and/or use and require different and separately burdensome manual/computer searches.

Accordingly, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (**e.g. a single defined compound**) in accordance with the above election of species above, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

For example, applicant must:

1. Identify a specific heterologous G-protein-coupled receptor species for a. AND
2. A Single peptide sequence corresponding to a species of "chimeric G-protein coupled receptor. This must include a specific G (alpha) subunit (when present) as illustrated in the Markush of claim 6.
3. Additionally, where a yeast gene mutation results in detection, applicant must elect a specific marker gene (e.g. a single gene as presented in Markush of claim 47).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

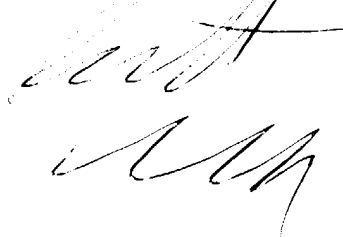
**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa  
Primary Examiner  
Art Unit 1639



BC  
July 19, 2004